

REMARKS

Claims 1-3, 7, 13-15, 17, 19, 21, 33-35, 38-40, and 49 have been amended, and claim 52 has been added. The pending claims are 1-4, 7-19, and 21-52.

The amendment to claims 1, 7, 13, 14, 21, 35, 38, 39, and 49 is supported by the specification at, for instance, page 8, line 18 through page 9, line 11.

The amendment to claims 2 and 3 is supported by originally filed claims 1, 5, and 6.

The amendment to claims 15, 17, and 19 is supported by originally filed claim 14 and by the specification at, for instance, page 13, lines 14-25.

New claim 52 is supported by originally filed claim 13 and the specification at, for instance, page 11, lines 1-3, and page 13, lines 14-15 and lines 22-25.

Summary of Interview

The Examiner is thanked for the courtesies extended to the undersigned during the interview of July 23, 2001, where the pending claims and the Office Action were discussed. This response is directed to those rejections of record in the Office Action.

Rejections under 35 U.S.C. §112, first paragraph (Enablement)

Claims 4, 10, 18, and 40 were rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for determining whether or not an individual has SCA8. This rejection is respectfully traversed.

Applicants submit that claims 4, 10, and 18 are enabled by the present application. Claims 4, 10, and 18 recite "a kit for detecting whether or not an individual has, or is at-risk for developing, spinocerebellar ataxia type 8." The claims further clearly recite the components of the kit, including oligonucleotide primers (claims 4 and 18) or a probe (claim 10), and the specification details how to use the primers and probes.

Regarding claim 40, it is respectfully submitted that the specification provides enablement for determining whether or not an individual has SCA8 (discussed in detail in the

E

Amendment and Response

Page 13

Applicant: Laura P.W. Ranum, et al.

Serial No.: 09/181,585

Title: SPINOCEREBELLAR ATAXIA TYPE 8 AND METHODS OF DETECTION

Amendment and Response mailed May 23, 2000). In the interests of furthering prosecution, claim 40 has been amended to delete "whether an individual has, or is at-risk for developing, spinocerebellar ataxia type 8" and insert "a method for determining whether an individual is at-risk for developing spinocerebellar ataxia type 8" therefor, thereby rendering the rejection moot. New claim 52 has been added and recites the subject matter no longer recited in amended claim 40. New claim 52 further recites "and wherein the individual displays at least one symptom of ataxia."

The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 4, 10, 18, and 40 under 37 C.F.R. §112, first paragraph.

Rejections under 35 U.S.C. §112, first paragraph (Written Description)

Claims 1, 4, 7, 9-14, 18, 21- 42, 49, 50, and 51 were rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Claims 1, 7, 9-14, 21-32, 35, 37-39, 41, 42, 49, and 51 were rejected because the recitation of "SCA8 coding sequence" reads on the SCA8 gene, which is asserted by the Examiner to not be taught in the specification. The Examiner is requested to note that independent claims 10, 27, 28, 31, 32, 41, and 42 do not recite "SCA8 coding sequence." Thus, it is respectfully submitted that claims 10, 27, 28, 31, and 32 should not be subject to this rejection.

Regarding claims 1, 7, 9, 11-14, 21-26, 29, 30, 35, 37-39, 49, and 51, it was asserted at page 6 of the Action that "SCA8 coding sequence" reads on the SCA8 gene, and that a gene includes introns, exons, and regulatory sequences. Applicants disagree with the assertion that "SCA8 coding sequence" includes regulatory sequences. The term "coding sequence" is defined in the specification as a nucleotide sequence that codes for an mRNA that may or may not be translated into a polypeptide when placed under the control of appropriate regulatory sequences (page 7, lines 16-20). Thus, a coding sequence includes the nucleotides that code for an mRNA,

E

Amendment and Response

Page 14

Applicant: Laura P.W. Ranum, et al.

Serial No.: 09/181,585

Title: SPINOCEREBELLAR ATAXIA TYPE 8 AND METHODS OF DETECTION

and does not include regulatory sequences, including, for instance, a promoter.

Independent claims 1, 7, 13, 14, 21, 35, 38, 39, and dependent claim 49 have been amended to recite the following:

"wherein the SCA8 coding sequence comprises a nucleotide sequence, the complement of which hybridizes to the nucleotide sequence set forth at SEQ ID NO:1 in a hybridization solution at 60°C for 3 hours, followed by two washes for 15 minutes each at room temperature in a solution containing 2x SSC and 0.05 % SDS, followed by two washes for 15 minutes each at 50°C in a solution containing 0.1% SSC and 0.1% SDS . . ."

It is respectfully submitted that this provides a precise definition that distinguishes the claimed subject matter from other materials. Since all SCA8 coding sequences must have a nucleotide sequence which hybridizes under the recited conditions, there is not substantial variation between the claimed SCA8 coding sequences. The species disclosed (SEQ ID NO:1) is representative of the genus because all members must have a nucleotide sequence which hybridizes under the recited conditions. Thus, one of skill in the art can, as one can do with a fully described genus, recognize the identity of the members of the genus.

Claims 33 and 34 were rejected because "the claims read on sequences that only need have 15 nucleotides from the designated nucleic acid sequences of SEQ ID NO:1." In the interests of furthering prosecution, claims 33 and 34 have been amended to recite "consisting essentially of."

Claims 10, 18, and 40 were rejected because the specification does not teach diagnosis. As discussed above in the response to the rejection under Rejections under 35 U.S.C. §112, first paragraph (Enablement), claims 10 and 18 recite "a kit for detecting whether or not an individual has, or is at-risk for developing, spinocerebellar ataxia type 8." The claims further clearly recite the components of the kit, including a probe (claim 10) or oligonucleotide primers (claim 18), and the nucleotide sequence of the probe and primers.

As discussed above under "Rejections under 35 U.S.C. §112, first paragraph (Enablement)," the present application teaches diagnosis. In the interests of furthering prosecution, claim 40 has been amended to delete "whether an individual has, or is at-risk for

E

Amendment and Response

Page 15

Applicant: Laura P.W. Ranum, et al.

Serial No.: 09/181,585

Title: SPINOCEREBELLAR ATAXIA TYPE 8 AND METHODS OF DETECTION

developing, spinocerebellar ataxia type 8" and recite "a method for determining whether an individual is at-risk for developing spinocerebellar ataxia type 8" therefor, thereby rendering the rejection moot. New claim 52 has been added and recites the subject matter no longer recited in amended claim 40. New claim 52 further recites "and wherein the individual displays at least one symptom of ataxia."

The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 4, 7, 9-14, 21- 42, 49, 50, and 51 under 37 C.F.R. §112, first paragraph.

Allowed claims

The Examiner is thanked for noting that claims 2-3, 15-17, 19, and 43-48 were enabled, adequately described, and free of the prior art. Claims 2-3, 15, 17, and 19 have been rewritten in independent form. Applicants respectfully disagree with the assertion in the Action that "[t]hese claims are drawn to methods and products that indicate a *predisposition* (not diagnosis) to SCA8" (emphasis in original). As discussed above under "Rejections under 35 U.S.C. §112, first paragraph (Enablement)," the present application teaches whether or not an individual has SCA8.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-305-1005) to facilitate prosecution of this application.

E

Amendment and Response

Page 16

Applicant: Laura P.W. Ranum, et al.

Serial No.: 09/181,585

Title: SPINOCEREBELLAR ATAXIA TYPE 8 AND METHODS OF DETECTION

If necessary for consideration and entry of this amendment and response, please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this 3rd day of August, 2001.

David L. Provence
David L. Provence

Date

DLP/mi

August 3, 2001

Respectfully submitted,
LAURA P.W. RANUM, ET AL.
By Applicants' Representatives,
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

By:

David L. Provence
David L. Provence

Reg. No. 43,022

Direct Dial (612) 305-1005

E